



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
-----------------	-------------	----------------------	---------------------

09/497,123 02/03/00 MESSERLI

D 8932-114

020582
PENNIE & EDMONDS LLP
1667 K STREET NW
SUITE 1000
WASHINGTON DC 20006

QM12/1222

EXAMINER

PELLEGRINO, B

ART UNIT

PAPER NUMBER

3738
DATE MAILED:

12/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/497,123

Applicant(s)

MESSERLI ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 22 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2, 3.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

Art Unit: 3738

DETAILED ACTION

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention: Species I, Figs. 1-9, 14 (claims 1-21); Species II, Figs. 10, 11 (claim 22); Species III, Figs. 12, 13 (claim 23).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

During a telephone conversation with Paul Bianco on 12/12/00 a provisional election was made without traverse to prosecute the invention of Species I, claims 1-21. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22 and 23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is an inconsistency between the language of the preamble which recites an "end member," and as to the scope of the claim. The limitation having the same material as the implant is indefinite since no implant is

positively claimed. Therefore, the scope of the claim is unclear as to what is intended to be claimed, the subcombination (end member) or the combination of the implant and the end member. The language of the claim must be consistent with the intent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4, 5, 6, 9, 12, 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by (RU 2008851). Fig. 1 shows an end member having a first portion 2 having a top surface and a second portion 1. The top surface is solid and can be construed as being annular and round. Additionally, the second portion has a hole 4. It can also be seen that the first portion has "channels" 3 in the anterolateral and anterior-posterior direction since the structure is cylindrical. See abstract.

Claims 1, 2, 4-8, 10, 11, 13, 14, 15, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Biedermann et al. (5702451). Fig. 6 shows an end member for insertion into an implant. It can be seen that the end member has a first portion 12 and a second portion 19. Biedermann et al. shows in Fig. 2 that the end member can be annular or round, col. 1, lines 61-64. Fig. 3 teaches that first portion having a top surface 13 which is oval in shape and has a plurality of teeth 15 extending outward and

has first and second "channels" 14. With respect to claims 10 and 11, it can be seen in Figs. 8 and 10 that the end member is wedge-shaped and has a first portion 20 joined to second portion 12. It can also be construed that the prongs 21 or "teeth" have channels established anterolaterally between the prongs, Attachment A. Regarding claim 13, the second portion has a protruberance 15 on its exterior end. With respect to claim 17, it can be seen (Fig. 11) that the second portion 12 has a plurality of tabs 15.

Claims 1, 4, 6, 9, 14, 19 are rejected under 35 U.S.C. 102(a) as being anticipated by Koros et al. (5980522). Fig. 8 teaches of an end member 140 having a first portion having a flat planar surface of which is solid and round. The top surface is joined to second portion 142. It can also be seen that the top surface has two holes (145, 146) of which can be construed as "channels." It is inherent that the end member is of the same material.

Claims 1-4, 5, 8, 12, 14, 21 are rejected under 35 U.S.C. 102(a) as being anticipated by Rabbe et al. (5776197). Fig. 3 shows an end member 22 having a first portion 35 and a second portion 37. Rabbe et al. teach to have two channels 47 which are opposite one another on an annular, solid top portion. Additionally, the top surface has a plurality of teeth 120 which are pyramid-shaped screwed into holes on the surface, see also Fig. 7. It can be construed that the top surface is oblong. It can be seen that the second portion has a hole or threaded bore 39 for set screw 24.

Claims 1-3, 7, 8, 12, 20 are rejected under 35 U.S.C. 102(a) as being anticipated by Coates et al. (5989289). Fig. 12 teaches a spacer having a top surface comprising a plurality of teeth pyramid in shape and a lower portion with a hole. It can be construed

that the top layer or portion has a channel between the two opposing sections of teeth. Regarding claims 7 and 8, see col. 8, lines 43-45. With respect to claim 20, see col. 2, lines 49-66 teaching that spacers can be made of allograft bone.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. in view of Kuslich et al. (5700291). Koros et al. is explained as before. Koros teaches to use a threaded end cap to secure into a spinal implant. However, what Koros et al. fail to teach is to use tabs as a means for securing an end member to a spinal implant. Kuslich et al. teach to use a spinal end cap having tabs to lock secure the cap in the implant, Fig. 7 and col. 5, lines 1-2. It would have been obvious to one of ordinary skill in the art to substitute the endcap locking means of Kuslich et al. in the end member of Koros et al. as it would permit an easier removal from the implant.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Paul et al. (6143033) teach to place channels in the anterolateral direction.

Wagner et al. (5683464) show a spinal implant having a plurality of teeth on its surface and can be made of bone material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 7:30am to 5pm. The examiner can also be reached on alternate Fridays.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino
November 28, 2000
TC 3700, AU 3738

Michael J. Milano
Primary Examiner